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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,342	12/26/2001	Audrey Goddard	P3030R1C5	4319

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,342	GODDARD ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-30 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27,29,30,33 and 34* is/are rejected.

7)☒ Claim(s) *28 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks, amendments, and declaration filed 28 October 2005 have been entered. Claims 22 – 30 and 32 – 34 are pending and under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Withdrawn Rejections and Objections

4. The following rejections and objections made in the previous office action are withdrawn:

1) The objection to the oath is withdrawn. The inventors whose changes were not initialed or dated have been deleted, so the issue is moot.

2) The rejections of claims 22 – 29 and 32 – 34 under 35 USC § 101 and the corresponding rejections under § 112 for lack of utility are withdrawn in light of applicant's arguments and the articles cited on p. 9 of the remarks filed 28 October 2005. The specification asserts that the claimed proteins are useful in treatment of kidney diseases wherein mesangial cells are damaged. This utility was recognized in the prior art. Hugo (1997. J Clin Invest 100:786-794) teaches that mesangial cells are lost in disease states and that replenishing these cells is useful (see abstract and first paragraph, for example). Proliferation of mesangial cells appears to be required for successful repair of glomeruli following renal injury (Hugo, p. 233). The examiner concedes that the claimed invention is useful.

Maintained Rejections and Objections

Claim Rejections - 35 USC §§ 101 and 112

5. Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The rejection of all claims under 35 USC § 101 was withdrawn, with the exception of claim 30, for the reasons set forth above. This rejection is maintained with respect to claim 30 for the following reasons.

Claim 30 encompasses amino acids 293 – 507 of SEQ ID NO:57. The specification provides evidence that SEQ ID NO:57 induces mesangial cell proliferation (Example 41). However there are no data as to whether this fragment of the protein is "positive" in the assay.

Furthermore, while Figure 26 identifies amino acids 273 – 292 as a transmembrane domain, there is no evidence in either the figure or the specification that residues 293 – 507 are in fact an extracellular region. Thus a skilled artisan would have reason to doubt any asserted utility with respect to the extracellular region. For example, on p. 126 the specification contemplates screening assays using proteins expressed in cells, wherein the proteins are receptors. Since there is no evidence that residues 293 – 507 are extracellular, the artisan would have reason to doubt that these residues could be displayed on the extracellular surface of the cells. As there is no evidence that this fragment of the protein is useful for anything, claim 30 remains rejected under § 101.

6. Claim 30 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 22 – 27 and 33 – 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins at least 95% identical to SEQ ID NO:57 which induce mesangial cell proliferation, does not reasonably provide enablement for any polypeptide, related by sequence identity or even 100% identical to, residues 293 – 507 of SEQ ID NO:57, or for those polypeptides 80%, 85%, or 90% identical to SEQ ID NO:57 which induce mesangial cell proliferation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The examiner concedes that it is within the skill of the artisan to make variant polypeptides and test for their ability to induce mesangial cell proliferation, wherein the variants are at least 95% identical to SEQ ID NO:57. However, as set forth in the previous office actions, as there are no working examples of proteins less than 100% identical to SEQ ID NO:57, nor is there guidance as to the regions which should be retained, changed, or deleted, making variants that are 80%, 85%, or 90% identical to SEQ ID NO:57 would require a large degree of experimentation. Given the state of the prior art and the lack of guidance in the specification, the amount of experimentation required on the part of the skilled artisan to make and then test these proteins would be undue.

To the extent that the claims encompass a polypeptide either comprising, or related to by sequence identity, the fragment from residues 293 – 507 of SEQ ID NO:57, there is not

sufficient enablement in the specification. There is no evidence that this fragment is useful for anything as it has not been tested in any assay (see the rejection of claim 30 under 35 USC 101 above). While Figure 26 identifies amino acids 273 – 292 as a transmembrane domain, there is no evidence in either the figure or the specification that residues 293 – 507 are in fact an extracellular region. Thus to the extent any contemplated use of this fragment relies on its being an extracellular domain, the artisan would have to resort to a large amount of experimentation in order to use the claimed invention. Because the field of protein domains is complex, the specification provides no working examples or guidance as to how to use this fragment, and there is not sufficient evidence that the fragment is extracellular, the large amount of experimentation needed to determine how to use this fragment would be undue for the skilled artisan.

8. Claims 22 – 26 and 33 – 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained for the reasons set forth in the previous office action and reiterated herein. Applicant argues on p. 11 of the remarks that the examiner ignored the limitation "wherein said isolated polypeptide has the ability to induce mesangial cell proliferation". That is not the case; the examiner made the rejection in light of the claim limitation. Claims 22 – 26 are genus claims; because they recite percentage identity limitations they necessarily encompass more than just SEQ ID NO:57, even though the claimed proteins must also induce mesangial cell proliferation. The specification does not disclose any sequences which fall within the scope of these genera other than SEQ ID NO:57. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to

recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

Here, applicant has only disclosed a single member of each of the claimed genera. There is no evidence that applicant was actually in possession of any other members of the genera. Applicant is directed to the flow chart on p. 9 of the Revised Written Description Interim Guidelines Training Materials, available on the internet at <http://www.uspto.gov/web/offices/pac/writtendesc.pdf>, which is analogous to the instant situation. Claims 22 – 26 are genus claims, but neither the art nor the specification discloses a representative number of species falling within the genus. There is not even identification of any particular portion of the structure at either the nucleic acid or amino acid level that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

9. Claims 22 – 27, 30, and 32 – 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims have been amended to delete "wherein the extracellular domain is", but still recite "amino acids 293 – 507". There is no disclosure of this region being the extracellular domain. Figure 26 of the specification indicates the location of a transmembrane domain, but there is no disclosure of which end of the protein is intracellular and which end is extracellular. Page 34 of the specification contemplates specific fragments of the protein, such as from about residue 27 to about residue 507 (line 16), but the examiner is unable to find support for the fragment from residues 293 – 507. Since there was not disclosure of which regions were intracellular or extraceullar in the specification, drawings, or claims as originally filed, or contemplation of residues 293 – 507, identification of such regions is deemed to be new matter.

Claim Rejections - 35 USC § 102

10. Claims 22 – 27, 29 – 30, and 33 – 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruben (US 2003/0100051, cited in previous office action).

The examiner concedes that the effective date of Ruben is 10 November 1999 for prior art purposes, as MPEP § 706.02(f) shows that international applications filed before 29 November 1999 are not to be relied upon. Thus the declaration by Goddard et al. filed 28 October 2005 under 37 CFR §1.131 is sufficient to overcome the rejection of claims 28 and 32 under 35 USC 102(e). However, the declaration filed on 28 October 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejection of claims 22 – 27, 29 – 30, and 33 - 34 reference. The declaration is not commensurate in scope with the claimed subject matter. The declaration provides evidence that applicant was in possession of SEQ ID NO:57 and the protein encoded by the full-length cDNA deposited with ATCC. However claims 22 – 26 are genus claims, drawn to polypeptides 80, 85, 90, 95, or 99% identical to SEQ ID NO:57 with certain properties. The declaration does not provide evidence that applicant was in possession of these genera prior to 10 November 1999, thus claims 22 – 26 and dependent claims 33 – 34 stand rejected. Claims 27 and 29 – 30 encompass the polypeptide without its signal peptide and residues 293 – 507 of the polypeptide; the declaration does not provide evidence that applicant was in possession of either of these fragments prior to the effective filing date of Ruben.

Conclusion

11. Claims 22 – 27, 29 – 30, and 33 – 34 are rejected.

12. Claims 28 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHARON TURNER, PH.D.
PRIMARY EXAMINER
1-4-06

Daniel E. Kolker, Ph.D.
January 4, 2006